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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,358	MIGALY, PETER	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39,41-43 and 48-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39,41-43 and 48-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *February 13, 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

This application claims benefit of provisional application 60/319436, filed July 20, 2002. Claims 1-39, 41-43, and 48-54 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted January 21, 2005 is acknowledged wherein claims 14 and 15 are amended, claims 44-47 are cancelled, and new claims 51-54 are introduced.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites a list of antipsychotic drugs, including, ORG 5222 and SM-9018. These names do not clearly and distinctly indicate a particular chemical compound, thus rendering the listing of drugs indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 7, 8, 11-12, 19, 23, 27, and 31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating

depression, cognitive distortions, smoking cessation, or nicotine withdrawal comprising administering certain antidepressants defined in the specification and prior art in combination with certain specific atypical antipsychotic drugs known to be useful for improving therapeutic outcomes in depression, does not reasonably provide enablement for such a method involving any antidepressant and any antipsychotic. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method of treating depression and other disorders by administering a combination of two drugs. It is claimed that the antipsychotic drug improves the therapeutic outcome even in patients not suffering from psychotic symptoms.

The state of the prior art: Combination therapy with antidepressants and atypical antipsychotic drugs has been taught in the prior art. The antipsychotic drugs known to

be useful in this method are of the newer, atypical variety. No general theory has been provided which would explain the usefulness of atypical antipsychotic drugs for treating depression, or determining which specific drugs are the most likely to be useful. Although a number of drug combinations have been tested and found to be useful, particularly combinations of a serotonin reuptake inhibitor with an atypical antipsychotic, many drugs of both types have not been tested. In particular, typical antipsychotics and dopamine system stabilizers such as aripiprazole have not been tested in the claimed methods.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: In the absence of any general theory explaining the action of atypical antipsychotic drugs to enhance therapeutic outcomes with antidepressants, it is not possible to predict the efficacy of any particular antipsychotic for this purpose absent experimental data. Because the terms antidepressant and antipsychotic both encompass a large number of drugs of varying structures and methods of action, and because antipsychotic drugs differ significantly from each other as disclosed in Applicant's specification, (p. 13, lines 11-15) no one example of group of related examples can be predictive for demonstrating the effectiveness of antidepressants combined with antipsychotics generally. Thus the effectiveness of a particular combination therapy of an antidepressant and an antipsychotic for the treatment of depression, cognitive distortions, smoking cessation, or nicotine withdrawal is unpredictable.

The Breadth of the claims: The claimed invention encompasses combination therapies of any antidepressant with any antipsychotic. In particular, it encompasses combinations in which the antipsychotic is a typical or an atypical antipsychotic, or a dopamine system stabilizer.

The amount of direction or guidance presented: Two hypothetical cases are given in order to illustrate possible uses of the claimed therapeutic method. (p. 16-17)

The presence or absence of working examples: No working examples of the claimed therapeutic methods is provided by Applicant.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as antidepressant/antipsychotic combination therapy. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the claimed invention, one skilled in the art would be required to determine the extent of antidepressants and antipsychotics useful in said methods. Because Applicant has provided no working examples, and because the state of the art is unpredictable, many different combinations would need to be tested in order to provide a comprehensive understanding of which combinations are or are not useful in the claimed method. These experiments would be repeated for each combination in animal models of depression, cognitive distortions, and nicotine addiction, in order to establish their suitability as therapeutic methods. It should be noted that evaluating psychological disorders such as depression and cognitive distortions in animals is more difficult than evaluating a therapy for a nonpsychological condition such as cancer or arthritis.

Animal experiments include, along with the actual administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Because of the unpredictability of the art and the lack of any generalized method for predicting the pharmacological properties of any arbitrarily chosen molecule, these animal experiments would need to be repeated many times, and involve the maintenance, killing, and disposal of many experimental animals, to establish the suitability or lack thereof for each compound found to possess the desired activity in vitro.

The scale of animal testing described in the preceding paragraphs would present an undue amount of unpredictable experimentation to require of anyone wishing to practice the invention.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the unpredictability of the art and the lack of guidance or working examples, Applicants fail to provide information sufficient to practice the claimed invention with every possible antidepressant and antipsychotic.

Claims 42, 48, 53, and 54 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating depression and associated conditions, does not reasonably provide enablement for preventing depression or the progression or relapse thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is drawn to a method of treating or preventing depression, relapse of depression, or various complications thereof, by administering to a patient in need thereof a combination of an antidepressant and an antipsychotic.

The state of the prior art: Combination therapy with antidepressants and atypical antipsychotic drugs has been taught in the prior art. The antipsychotic drugs known to be useful in this method are of the newer, atypical variety. No general theory has been provided which would explain the usefulness of atypical antipsychotic drugs for treating

depression, or determining which specific drugs are the most likely to be useful. The prior art does not teach a method of preventing recurrence or relapse of depression through antidepressant/antipsychotic combination therapy. As evidenced by the existence of treatment-resistant cases of depression, no therapy is 100% effective at preventing the progression, recurrence, or relapse of depression.

Similarly, treatments for smoking cessation and nicotine addiction generally have a high rate of failure and relapse. No treatment has been found that can perfectly prevent relapse of smokers attempting to quit. A smoker who is not exceptionally committed to quitting will eventually start smoking again regardless of which drugs are administered.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: In the absence of any general theory explaining the action of atypical antipsychotic drugs to enhance therapeutic outcomes with antidepressants, it is not possible to predict the efficacy of any particular antipsychotic for this purpose absent experimental data. Because the terms antidepressant and antipsychotic both encompass a large number of drugs of varying structures and methods of action, and because antipsychotic drugs differ significantly from each other as disclosed in Applicant's specification, (p. 13, lines 11-15) no one example of group of related examples can be predictive for demonstrating the effectiveness of antidepressants combined with antipsychotics generally.

Furthermore, depression denotes an observed symptom rather than an underlying condition. Different cases of depression differ from one another to the extent

that a skilled practitioner must determine the best course of therapy empirically by administering one drug after another to a patient in order to find one which elicits a positive response. Thus it is highly unlikely that it is possible in all cases of depression to prevent progression, recurrence, or relapse with 100% certainty. Thus the prevention of progression, recurrence or relapse of depression is highly unpredictable.

In the case of cognitive distortions, smoking cessation, and nicotine addiction, the art is even more unpredictable. Both cognitive distortions and addictions have a strong psychological component, and the motivation of a patient to change is an essential factor in determining treatment outcome, and one which cannot be improved by any drug therapy. In particular, smoking cessation is rather difficult even with the aid of drug therapy, and most smokers who attempt to quit eventually suffer a relapse and start smoking again. Thus the treatment outcome in the treatment of cognitive distortions and nicotine addiction is highly unpredictable.

The Breadth of the claims: The claimed invention encompasses combination therapies of any antidepressant with any antipsychotic. In particular, it encompasses combinations in which the antipsychotic is a typical or an atypical antipsychotic, or a dopamine system stabilizer. Prevention is interpreted to mean the complete, 100% effective elimination of any progression, recurrence, or relapse of the disease while the patient is maintained on the therapy.

The amount of direction or guidance presented: Two hypothetical cases are given in order to illustrate possible uses of the claimed therapeutic method. (p. 16-17) No reason is given to suppose that he claimed methods are perfectly effective at

preventing progression, recurrence, or relapse of any instance of major depressive disorder,

The presence or absence of working examples: No working examples of the claimed therapeutic methods is provided by Applicant.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the prevention of disease. See MPEP 2164.

The quantity of experimentation necessary: The short-term usefulness of a therapy for relief of symptoms is no guarantee of its long-term usefulness for prevention of disease. Because no guidance is given for the use of the claimed therapeutic method for the long-term prevention of disease, one skilled in the art wishing to practice the invention would be unable to do so without first gathering information as to the long-term effectiveness of the therapy. Furthermore, in order to prevent recurrence of depression, cognitive distortion, or nicotine addiction as described above, the claimed therapeutic method, which comprises nothing more than administering a drug, must be able to fully counteract the effects of genetics and psychology in order to prevent the subject from ever becoming depressed, having distorted cognition, or smoking again, regardless of the subject's motivation, or any environmental stresses which may encourage the re-emergence of the subject's condition. Such a method would represent a significant novel improvement beyond anything disclosed in the prior art or in Applicant's disclosure, particularly in light of the high relapse rate for smokers attempting to quit.

In order to develop such a method in the absence of any existing data, one skilled in the art, in order to practice the invention, would undertake long-term human or animal tests in order to study the effectiveness of the claimed therapy for preventing recurrence or relapse after the initial recovery. Animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Human tests impose additional ethical and regulatory burdens.

Performing these studies with no guidance from Applicant or from the prior art is an undue amount of experimentation needed in order to practice the full range of the claimed invention.

Genetech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the lack of precedent in the art for prevention of relapse and the lack of guidance from Applicant's disclosure, Applicants fail to provide information sufficient to practice the claimed invention for the prevention of regression, recurrence, or relapse of disease.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-6, 9, 11, 13, 14, 16-18, 20-22, 24-26, 28-30, 32-35, 37-38, 42, 48, 49, 51, 53, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Tollefson. (PCT international publication WO99/61027, included by applicant with PTO-1449) Tollefson discloses a method of treating depression by administering both a serotonin reuptake inhibitor and an atypical antipsychotic. While one embodiment of this invention is a method of treating treatment-resistant depression, another embodiment is a method of providing rapid onset treatment of depression to a patient, (p. 2, lines 10-13) which is drawn to cases which have not demonstrated treatment resistance. This method anticipates instant claims 1-4, 9, 11, 37, 42, 48, and 49. Note that depression is interpreted as being a cognitive distortion with functional impairment and health hazards according to instant claim 3. Specific atypical antipsychotic drugs which may be administered in this method are olanzapine, clozapine, risperidone, sertindole, quetiapine, and ziprasidone. (p. 3) Specific serotonin reuptake inhibitors

which may be used are fluoxitene, duloxetine, venlafaxine, milnacipran, citalopram, fluvoxamine, paroxetine, and sertaline, (p. 4, line 5 – p. 5, line 14) anticipating instant claims 5, 6, 14, 16-18, 20-22, 24-26, 28-30, 32-35. Specific preferred embodiments utilize drug combinations listed on p. 5, line 23 – p. 6, line 1. All of the drugs included in the invention may be administered orally, (p. 14, lines 19-22) anticipating instant claim 38.

The claimed invention is thus anticipated by Tollefson.

Claims 1-2, 4-6, 9-11, 13-14, 37-38, 42, 48, 51, 53, and 54 are rejected under 35 U.S.C. 102(e) as being anticipated by Faour et al. (US patent application, 09/728276, Pub. No. 2001/0048943 A1, cited in PTO-1449) Faour et al. discloses, "a method of treating **depression, anxiety**, and/or psychosis in a mammal, the method comprising administering an osmotic device which provides a controlled release of VFX [Venlafaxine, a selective serotonin and norenepherin reuptake inhibitor] from its core and a rapid release of an anti-psychotic agent from an external coat," (p. 2, left column, paragraph 0020) anticipating instant claims 1-3, 9, 11, 13, 14, 37, 42, 48, 49, 51, 53, and 54. This osmotic device is meant for oral administration, anticipating instant claim 38. Various embodiments of the invention of Faour et al. include a number of atypical antipsychotic drugs, (p. 2, left column, paragraph 0022-0023) including those recited in instant claims 5, 6, and 10. The instant claims are thus anticipated by Faour et al.

Claims 3-6, 9, 49, 50, and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by George et al. (Reference included with PTO-892) George et al. discloses a clinical trial of bupropion for smoking cessation among schizophrenic patients. (p. 54, right column, second paragraph, p. 56, left column, figure 1) As these subjects were also being administered antipsychotic drugs for their schizophrenia, the varying effects of typical vs. atypical antipsychotics was also observed. (p. 56, right column, figure 3) Subjects taking atypical antipsychotics, in this case clozapine, risperidone, and olanzapine, were notably more likely to successfully abstain from smoking. (p. 56, right column, last paragraph – p. 57 left column, first paragraph) Thus George et al. discloses a method of treating a patient undergoing nicotine withdrawal or smoking cessation comprising administering to said patient an effective amount of an antidepressant in combination with an antipsychotic drug. Therefore the disclosure of George et al. anticipates the claimed invention.

Claims 1-2, 4, 7, 9, 11-15, 37, 38, 42, 48, and 51-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Chappell et al. (US patent application 10/001827, Pub. Number 2002/0094986 A1, cited in PTO-892) Chappell et al. discloses a method of treating depression, anxiety, or psychosis in a mammal by administering a combination of an antidepressant, a D4 receptor antagonist, (an antipsychotic) and a pharmaceutically acceptable carrier, anticipating instant claims 1-4, 7, 9, 37, 42, 48, and 49. (p. 1, left column, paragraph 0002) General types of antidepressants which may be used are listed in paragraph 0021 and include norepinephrine reuptake inhibitors,

serotonin reuptake inhibitors, and monoamine oxidase inhibitors, among others, anticipating instant claims 11-13. Norepinephrine reuptake inhibitors which may be used are listed in paragraph 0023 and include clomipramine among others, anticipating instant claims 14 and 15. The compounds used in this invention may all be administered orally, anticipating instant claim 38. (p. 22, paragraphs 0460-0462) Chappell et al. thus anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 36, 39, 41, 43, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tollefson. (PCT international publication WO99/61027, included by applicant with PTO-1449) Tollefson discloses a method of treating depression by administering both a serotonin reuptake inhibitor and an atypical antipsychotic. While one embodiment of this invention is a method of treating treatment-resistant depression, another embodiment is a method of providing rapid onset treatment of depression to a patient, (p. 2, lines 10-13) which is drawn to cases which have not demonstrated treatment resistance. Specific atypical antipsychotic drugs which may be administered in this method are olanzapine, clozapine, risperidone, sertindole, quetiapine, and ziprasidone. (p. 3) Specific serotonin reuptake inhibitors which may be used are

fluoxitene, duloxetine, venlafaxine, milnacipran, citalopram, fluvoxamine, paroxetine, and sertaline, (p. 4, line 5 – p. 5, line 14) Recommended dosages are given on p. 13. Tollefson does not disclose a method in which the antipsychotic is administered according to the dosage levels disclosed in instant claim 36. Tollefson does not disclose a method of administering the claimed treatments as soon as possible , or a method wherein treatment is given for preventing suicide. Tollefson also does not explicitly disclose a method of treating cognitive distortions as defined by Applicant's specification on p. 15, lines 9-14.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use aripiprazole as the atypical antipsychotic in the methods disclosed by Tollefson et al. It would have been obvious to one of ordinary skill in the art to administer the drugs in the methods of Tollefson et al. at the dosages describes in instant claim 36. It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the therapeutic method of Tollefson to a patient as initial treatment as soon as possible, and to provide treatment in order to prevent suicide, as described in instant claims 39, 41, and 43, and to treat cognitive distortions according to instant claims 3 and 49. One of ordinary skill in the art would have been motivated to practice the therapeutic method in this way because Tollefson discloses that his method is useful for providing rapid onset treatment, and thus for providing immediate treatment for emergency cases where time is of the essence, such as those in which the subject is at serious risk of suicide. One of ordinary skill in the art would have been motivated to use the doses described in instant claim 36 because the ranges

disclosed in this claim overlap with those disclosed on p. 13 of Tollefson et al. One of ordinary skill in the art would have been motivated to use the method for treating cognitive distortions because cognitive distortions as defined by Applicant are often associated with depression. One of ordinary skill in the art would reasonably have expected success in using the dosages of instant claim 36 because these dosages overlap with those taught by Tollefson et al. and because adjusting dosages within the general range known in the prior art is well within the level of ordinary skill in the art. One of ordinary skill in the art would reasonably have expected success in administering treatment as soon as possible to prevent suicide because suicide is known to correlate strongly with depression, and because treating a subject for a serious condition as son as possible is a generally recognized practice in the art. One of ordinary skill in the art would reasonably have expected success in treating cognitive distortions because treating the associated depression would lead to improvement in the associated cognitive distortions.

Thus the invention taken as a whole is *prima facie* obvious.

Summary

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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